



26874

PATENT TRADEMARK OFFICE

**IN THE UNITED STATES PATENT & TRADEMARK OFFICE**

Applicant: David Witte, et al. : Docket No: 10872/482274

Serial No. 10/074,620 ✓ : Group Art Unit:

Filed: February 13, 2002 : Examiner:

For: QUANTITATIVE EPSTEIN BARR VIRUS PCR RAPID ASSAY

**RECEIVED**

NOV 27 2002

**INFORMATION DISCLOSURE STATEMENT**

TECH CENTER 1600/2900

THE ASSISTANT COMMISSIONER FOR PATENTS  
Washington, D.C. 20231

Dear Sir:

In accordance with 37 C.F.R. §§1.97 and 1.98, Applicant herewith submits certain patent references and other information, which the Patent & Trademark Office may wish to consider in examining the above-identified application. The references and information are provided below, and are also listed on the attached Form PTO-1449.

<b><u>REFERENCES</u></b>	<b><u>INVENTOR</u></b>	<b><u>ISSUE DATE</u></b>
4,683,195	Mullis, et al.	Jul. 28, 1987
4,683,202	Mullis	Jul. 28, 1987
5,455,175	Wittwer, et al.	Oct. 3, 1995
5,837,832	Chee, et al.	Nov. 17, 1998
5,807,522	Brown et al.	Sep. 15, 1998

**OTHER REFERENCES****Reference:**

*A simple introduction to the science of the polymerase chain reaction*, PCR: Basics for beginners, Jan. 31, 01.

*Adaptation Protocol for Sequence-Specific Detection of DNA with Hybridization Probes*, Roche Molecular Biochemicals, Technical Note. No. 3/99.

Antin, J. et al., *Selective depletion of bone marrow T lymphocytes with anti-CD5 monoclonal antibodies: Effective prophylaxis for graft-vs-host disease in patients with hematologic malignancies*. Blood: 78: 2139, 1991.

Baldanti F, et al., *High levels of Epstein-Barr virus DNA in blood of solid organ transplant recipients and their value in predicting posttransplant lymphoproliferative disorders*. J. Clin Microbiol. 38: 613, 2000.

Caplin, et al., *The most direct way to monitor PCR amplification for quantification and mutation detection*, Roche Molecular Biochemicals, Biochemica - No. 1, 1999.

*Choice of Suitable Probe Targets*, 1 page article.

DeSilva, et al., *Rapid Genotyping and Quantification on the LightCycler™ with Hybridization Probes*, Biochemica, No. 2, (1998).

Groen, Pamela, et al., "Development of a Quantitative EBV PCR Assay for the LightCycler System," 14 pgs, (2001).

Henry T., et al., *Correlation of Epstein-Barr viral load with development of PTLN in solid organ transplant recipients*. (In press). (Article Unavailable)

Ho M., et al. *The frequency of Epstein-Barr virus infection and associated lymphoproliferative syndrome after transplantation and its manifestations in children*, Transplantation 45: 719-727, 1988.

Kenagy DN, et al., *Epstein-Barr virus DNA in peripheral blood leukocytes with post-transplant lymphoproliferative disease*. Transplant 60:547, 1995.

Kimura H., et al., *Quantitative analysis of Epstein-Barr virus load by using a real-time PCR assay*. J. Clin Microbiol. 37:132, 1999.

Landt, et al., *Selection of Hybridization Probe Sequences for Use with the LightCycler*, Roche Molecular Biochemicals, Technical Note No. LC6/99.

*LightCycler Principles*, Biochem.Boehringer-Mannheim.

Loechelt, Brett J., et al., "GM-CSF as Pre-Emptive Therapy for Post-Transplant EBV Disease," 3 pgs, (2001).

Lucas KG, et al., *Semiquantitative Epstein-Barr virus DNA in blood of solid organ transplant recipients and their value in predicting posttransplant lymphoproliferative disorders*. J. Clin Microbiol. 38: 613, 2000. (Article Unavailable)

Martell, M., et al., *High-throughput real-time reverse transcription-PCR quantitation of hepatitis C virus RNA*. J. Clin. Microbiol. 1999 Feb;37(2):327-32.

Martin, PJ, et al., *Fatal Epstein-Barr virus associated proliferation of donor B cells after treatment of acute graft vs-host disease with a murine anti-T-cell antibody*. Ann Intern Med 101:310, 1984.

Mercier B., et al., *Simultaneous screening for HBV DNA and HCV RNA genomes in blood donations using a novel TaqMan PCR assay*. J. Clin Methods, 1999 Jan;37(1):1-9.

Niesters H, et al, *Development of a real-time quantitative assay for detection of Epstein-Barr virus*. J. Clin Microbiol. 2000 Feb;38(2):712-5.

Papadopoulos EB, et al., *Infusions of donor leukocytes as treatment of Epstein-Barr virus associated lymphoproliferative disorder complicating allogeneic marrow transplantation*, N. Engl J. Med 330: 1185, 1994.

Rasmussen et al., *Quantitative PCR by Continuous Fluorescence Monitoring of a Double Strand DNA Specific Binding Dye*, Biochemica, No. 2, (1998).

Recombinant DNA Technology, *DNA Amplification by the Polymerase Chain Reaction*, Chapter 3, Nucleotides and Nucleic Acids.

Riddler SA, et al., *Increased levels of circulating Epstein-Barr virus (EBV) infected lymphocytes and decreased EBV nuclear antigen antibody responses are associated with the development of post-transplant lymphoproliferative disease in solid-organ transplant recipients*. Blood 84:972, 1994.

Rogers B, et al., *Epstein-Barr virus polymerase chain reaction and serology in pediatric post-transplant lymphoproliferative disorder: three year experience*. Pediatric & Developmental Pathology 1: 480, 1998.

Savoie A, et al., *Direct correlation between the load of Epstein-Barr virus infected lymphocytes in the peripheral blood of pediatric transplant patients and risk of lymphoproliferative disease*. Blood 83: 2715, 1994.

Shapiro, RS, et al., *Epstein-Barr virus associated B-cell lymphoproliferative disorders following bone marrow transplantation*. Blood 71: 1234, 1988.

Starzl T, et al., *Reversibility of lymphomas and lymphoproliferative lesions developing under cyclosporin steroid therapy*, Lancet I: 583, 1984.

*The LightCycler™ - the Smartest Innovation for More Efficient PCR*, Biochemica, No. 2 (1998).

University of Chicago Cancer Research Center, DNA Sequencing Facility, *The Standard Primers*, April 17, 1997 update.

Zutter MM, et al. *Epstein-Barr virus lymphoproliferation after bone marrow transplantation*. Blood 72, 520, 1988.

Copies of the listed references are provided. No representation is made or intended that a prior art search has been made or that no better art than the listed is available. It is respectfully requested that the information be considered by the Examiner and made of record in the present application.

The Assistant Commissioner for Patents is authorized to charge any deficiency or credit any overpayment to Frost Brown Todd LLC Deposit Account No. 06-2226.



Stephen R. Albainy-Jenei  
Registration No. 41,487  
Telephone (513) 651-6839  
FROST BROWN TODD LLC  
2200 PNC Center  
201 East Fifth Street  
Cincinnati, Ohio 45202-4182

November 20, 2002

**CERTIFICATE OF MAILING**

I hereby certify that a copy of this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to The Assistant Commissioner of Patents, Washington, D.C. 20231 this 22<sup>nd</sup> day of November, 2002.

